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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,295	08/23/2006	Yoshihiro Murakami	294884US0PCT	6991

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EXAMINER	
PERREIRA, MELISSA JEAN	
ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
05/13/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/590,295	MURAKAMI ET AL.	
	Examiner	Art Unit	
	MELISSA PERREIRA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 April 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) *3* is/are withdrawn from consideration.

5)☒ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 4-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/23/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of the species formula IV in the reply filed on 4/13/10 is acknowledged. The traversal is on the ground(s) that no adequate reasons and/or examples have been provided to support a conclusion of patentable distinctiveness between the identified groups. This is not found persuasive because the restriction/election mailed 3/30/10 states that the species have different chemical structures and each would require a different search, thus, causing a search burden to the office. The requirement is still deemed proper and is therefore made FINAL.

2. Claim 3 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 4/13/10.

Information Disclosure Statement

3. The information disclosure statement filed 8/23/06 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein/lined through has not been considered.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear as to the meaning of the recitation, "ar(lower)alkoxycarbonylamino, ar(lower)alkoxy" as the term ar(lower) is confusing.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1 and 7 rejected under 35 U.S.C. 102(b) as being anticipated by Lister-James et al. (*J. Nucl. Med.***1996**, *37*, 775-781).

8. Lister-James et al. (*J. Nucl. Med.***1996**, *37*, 775-781) teaches of ^{99m}Tc-P280 having high affinity and specificity for the GPIIb/IIIa receptor expressed on activated platelets, for use as a thrombus imaging agent (abstract; p775, last paragraph). Lister-James et al. further teaches of the method of detecting a thrombus via the

administration of ^{99m}Tc-P280 into dogs and imaged via gamma camera imaging (p776, Imaging studies; figure 3).

9. The thrombus imaging agent of the disclosure anticipates the contrast medium for thrombus of the instant claims and are capable of the same functions, such as binding to glycoprotein IIb/IIIa and have the same properties.

10. It is respectfully pointed out that instant claim 1 is a product-by-process limitation. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed Cir. 1985). See MPEP 2113.

11. Claims 1,4,5,7 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by DeGrado et al. (US 5,879,657).

12. DeGrado et al. (US 5,879,657) teaches of radiolabeled cyclic compounds which acts as antagonists of the platelet glycoprotein IIb/IIIa complex and the method of using the radiolabeled cyclic compounds as imaging agents for the diagnosis or arterial and venous thrombi (abstract; column 2, lines 30-38; columns 43 and 44). The radiolabel may be ^{11}C, ^{18}F, etc. (column 61, lines 29+). Once the radiolabeled compounds are administered, the presence of thrombi may be visualized using a standard radioscintographic imaging system, such as PET, SPECT, etc. (column 203, lines 34+).

Also, the radiolabeled cyclic compounds may be useful in treating a thrombus formation (column 205, lines 63+).

13. The radiolabeled compounds of the disclosure anticipate the contrast medium for thrombus of the instant claims and are capable of the same functions, such as binding to glycoprotein IIb/IIIa and have the same properties.

14. It is respectfully pointed out that instant claims 1,4 and 5 are product-by-process limitations. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed Cir. 1985). See MPEP 2113.

15. Claims 1,4 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Srinivasan et al. (US 6,132,697).

16. Srinivasan et al. (US 6,132,697) teaches of a radiopharmaceutical capable of localizing at a site of thrombus containing activated platelets within a mammalian body wherein the radiopharmaceutical is a peptidomimetic containing ligand capable of specifically binding to the GPIIb/IIIa integrin receptor of platelets in the thrombus (abstract). The method of imaging a site of thrombus in a mammalian body occurs via the administration of a diagnostically effective amount of the radiopharmaceutical composition of this invention complexed with a selected diagnostic metal radionuclide,

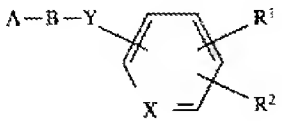
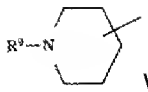
such as positron-emitting radionuclides in a pharmaceutically acceptable carrier (column 2, lines 61+; column 3, lines 13-23; column 8, lines 46-50). The radiopharmaceuticals may be used to provide therapy to sites of thrombus (column 3, lines 13-23).

17. The radiopharmaceuticals of the disclosure anticipate the contrast medium for thrombus of the instant claims and are capable of the same functions, such as binding to glycoprotein IIb/IIIa and have the same properties.

18. It is respectfully pointed out that instant claims 1 and 4 are product-by-process limitations. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed Cir. 1985). See MPEP 2113.

19. Claims 1,2,6 and 7 are rejected under 35 U.S.C. 102(e) as being anticipated by Katano et al. (US 5,594,004).

20. Katano et al. (US 5,594,004) teaches of the compounds and pharmaceutical compositions of formula (I) (below) which are GPIIb/IIIa antagonists and are used for inhibiting the aggregation of platelets and for the treatment of thrombotic diseases (column 1, lines 9-15 and 50+; all of column 2; column 10, lines 28+).

21.  (I) A represents  wherein R^9 represents hydrogen, etc.; B represents C_{2-6} alkenylene, etc.; Y represents $-(CO)_k-N(R^5)-Z-$ wherein R^5 is lower alkyl, etc., k is 0 or 1, Z is $-(CH_2)_m-CO-$, etc. and m is 1-3; X represents CH, etc.; R^1 and R^2 represent $-W-(CH_2)_i-COOR^3$ wherein W is OR^4, i is 1-4 and R^3 is hydrogen, etc. (all of column 2; column 3, lines 1-32). The pharmaceutical compositions of the disclosure can be administered to human subjects through any one of routes, such as i.v., etc. (column 10, lines 28+).

22. The compounds of the disclosure anticipate the contrast medium for thrombus and compound of formula IV of the instant claims and are capable of the same functions, such as binding to glycoprotein IIb/IIIa and have the same properties.

23. It is respectfully pointed out that instant claims 1 and 2 are product-by-process limitations. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed Cir. 1985). See MPEP 2113.

Claim Rejections - 35 USC § 103

24. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

25. Claims 1,2,4-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeGrado et al. (US 5,879,657) in view of Katano et al. (US 5,594,004).

26. DeGrado et al. (US 5,879,657) discloses radiolabeled cyclic compounds which acts as antagonists of the platelet glycoprotein IIb/IIIa complex and the method of using the radiolabeled cyclic compounds as imaging agents for the diagnosis or arterial and venous thrombi (abstract; column 2, lines 30-38; columns 43 and 44). The radiolabel may be ^{11}C, ^{18}F, etc. (column 61, lines 29+). Once the radiolabeled compounds are administered, the presence of thrombi may be visualized using a standard radioscintographic imaging system, such as PET, SPECT, etc. (column 203, lines 34+). DeGrado et al. does not disclose the compounds of the instant claims 2 and 3.

27. Katano et al. (US 5,594,004) teaches of the compounds and pharmaceutical compositions of formula (I) (below) which are GPIIb/IIIa antagonists and are used for inhibiting the aggregation of platelets and for the treatment of thrombotic diseases (column 1, lines 9-15 and 50+; all of column 2; column 10, lines 28+) as well as that stated above.

28. At the time of the invention it would have been obvious to one ordinarily skilled in the art to substitute the pharmaceutical compositions of Katano et al. for the cyclic compounds of DeGrado et al. as the compounds of both disclosures are glycoprotein IIb/IIIa antagonists and are used for the method of treating thrombus formation. It would have been advantageous to label the pharmaceutical compositions of Katano et al. to

visualize the presence of thrombi using the imaging techniques of DeGrado et al. for the method of treating thrombus. It is obvious to those skilled in the art to make known substitutions on compounds that are similar in structure and function to observe the effects on the function of such compounds and to use the observations/data to further manipulate a compound to generate the desired effect, such as enhanced thrombus detection.

29. It is respectfully pointed out that instant claims 1,2,4 and 5 are product-by-process limitations. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed Cir. 1985). See MPEP 2113.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA PERREIRA whose telephone number is (571)272-1354. The examiner can normally be reached on 9am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/Melissa Perreira/
Examiner, Art Unit 1618